

15093700

MAR - 4 2010

510(k) Summary

| | |
|---------------------|--|
| Introduction | According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence. |
|---------------------|--|

| | |
|---|--|
| Submitter name, address, contact | <p>Roche Diagnostics 9115 Hague Road, P.O. Box 50416 Indianapolis, IN 46250-0416 317-521-3577</p> <p>Contact Person: Kelly Colleen O'Maine Adams Phone: 317-521-3577 Fax: 317-521-2324 Email: colleen.adams@roche.com</p> <p>Secondary Contact: Stephanie Greeman Phone: 317-521-2458 Fax: 317-521-2324 Email: stephanie.greeman@roche.com</p> <p>Date Prepared: November 30, 2009</p> |
|---|--|

| | |
|--------------------|--|
| Device Name | <p>Proprietary name: Elecsys HCG STAT CalCheck 5 Common name: HCG STAT CalCheck 5 Classification name: Single (specified) analyte controls (assayed and unassayed)</p> |
|--------------------|--|

| | |
|-------------------------|--|
| Predicate device | The Elecsys HCG STAT CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys HCG+ β CalCheck 5 (K092168). |
|-------------------------|--|

| | |
|---------------------------|--|
| Dévice Description | The Elecsys HCG STAT CalCheck 5 is a lyophilized product consisting of HCG in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels. |
|---------------------------|--|

| | |
|---------------------|---|
| Intended use | The Elecsys HCG STAT CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys HCG STAT reagent on the indicated Elecsys and cobas e immunoassay analyzers. |
|---------------------|---|

Continued on next page

510(k) Summary, Continued

Comparison Table The table below compares Elecsys HCG STAT CalCheck 5 with the predicate device, Elecsys HCG+ β Calcheck 5 (K092168).

| Characteristic | Elecsys HCG+ β CalCheck 5 (K092168) | Elecsys HCG STAT CalCheck 5 |
|----------------|---|---|
| Intended Use | The Elecsys HCG+ β CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys HCG+ β reagent on the indicated Elecsys and cobas e immunoassay analyzers. | The Elecsys HCG STAT CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys HCG STAT reagent on the indicated Elecsys and cobas e immunoassay analyzers. |
| Levels | Five | Five |
| Format | Lyophilized | Lyophilized |
| Handling | Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion. | Same |
| Stability | <u>Unopened:</u> <ul style="list-style-type: none">• Store at 2-8°C until expiration date <u>Reconstituted:</u> <ul style="list-style-type: none">• 20 – 25°C : 4 hrs | Same |
| Matrix | Human serum matrix | Same |

Performance Characteristics The Elecsys HCG STAT CalCheck 5 was evaluated for value assignment. Because Elecsys HCG STAT CalCheck 5 formulation is identical to the Elecsys HCG+ β CalCheck 5, the stability studies presented and cleared in the HCG+ β CalCheck 5 submission, K092168, apply.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Roche Diagnostics Corp
c/o Kelly C. O'Maine Adams
9115 Hague Road
PO Box 50410
Indianapolis, Indiana 46250-0416

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

MAR 04 2010

Re: k093700
Trade Name: ELECYS HCG STAT CALCHECK 5
Regulation Number: 21 CFR §862.1660
Regulation Name: Calibrator.
Regulatory Class: Class I
Product Codes: JJX
Dated: February 8, 2010
Received: February 12, 2010

Dear Ms. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

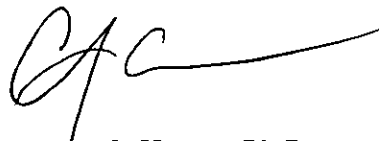
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K093700

Device Name: Elecsys HCG STAT CalCheck 5

Indication For Use:

The Elecsys HCG STAT CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys HCG STAT reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093700